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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/823,175 | 04/13/2004 | Mary J. Ruwart | RUW-1001 | 6078 |

7590 10/06/2005
Nancy Lord Johnson, Ltd.
Suite 3
361 South Frontage Rd.
Pahrump, NV 89048

EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

| ART UNIT | PAPER NUMBER |
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1655

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED
OIPE/IAP
OCT 26 2005

Office Action Summary

Application No.

10/823,175

Applicant(s)

RUWART, MARY J.

Examiner

S. B. McCormick-Ewoldt

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1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-17 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant has cancelled the claims drawn to different inventions so the restriction requirement is moot.

Claims Pending

Applicant has cancelled claims 2, 18-29. Claims 1 and 3-17 will be examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mease *et al.* (US 6,201,022 B1), McClung (US 6,579,543 B1) and Murad (US 2003/0007930).

Mease *et al.* (US 6,201,022 B1) discloses a composition with omega-3, that contains eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and gamma-linolenic acid (GLA)), a pharmaceutical acceptable carrier such as cocoa butter and vitamin E (i.e. tocopherols) to be used in a composition for treating neuritic pain syndrome such as brought on by burns (column 3, lines 62-67; column 4, lines 57-67 and column 5, lines 2-8, 53-55; Table 2 and Example 11). Mease *et al.* do not disclose using lavender oil, Sodium PCA or Methyl-Sulfonyl-Methane.

McClung (US 6,579,543 B1) discloses a composition to be applied for relief of pain brought and by burns and sunburns. The composition contains methyl-sulfonyl-methane (MSM) lavender and omega-3 (column 2, lines 25-35, 67; column 3, lines 46-56; column 4, lines 16-46; column 17, lines 22-23, 55).

Murad (US 2003/0007930) discloses a topical composition for dermatological conditions caused by aging or by extrinsic factors such as sunlight or radiation and wrinkles and sun

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damaged skin. The composition contains hydrophic agents such as tocopherols (vitamin E) and moisturizing agents such as sodium PCA and omega-3 which contains gamma-linolenic acid ([0043], 0044), [0053], [0054], [0055]).

These references taken together disclose a composition that comprises omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane that can be used to relieve pain due to burns. Thus, a person of ordinary skill in the art would reasonably expect that omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane would be used to relieve pain from burns as taught by the references. Based on this reasonable expectation of success, a person of ordinary skill in the art would be motivated to modify the teachings of the references.

These references show that it was well known in the art at the time of the invention to use omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane in compositions that aid in relief from burns and other dermatitis conditions. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane are used in compositions that aid in relief from burns and other dermatitis conditions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions aid in relief from burns and other dermatitis conditions. Therefore, the artisan would have been motivated to combine omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

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The references also do not specifically teach the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe
9-27-05

SUSAN COE
PRIMARY EXAMINER

| | | | |
|-----------------------------------|---------------------------------------|---|-------------|
| Notice of References Cited | Application/Control No. 10/823,175 | Applicant(s)/Patent Under Reexamination RUWART, MARY J. | |
| | Examiner S. B. McCormick-Ewoldt | Art Unit 1655 | Page 1 of 1 |

U.S. PATENT DOCUMENTS

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|---|--|-----------------|--------------------|----------------|
| * | A | US-6,201,022 B1 | 03-2001 | Mease et al. | 514/560 |
| * | B | US-6,579,543 B1 | 06-2003 | McClung, Jackie H. | 424/728 |
| * | C | US-2003/0007939 A1 | 01-2003 | Murad, Howard | 424/61 |
| | D | US- | | | |
| | E | US- | | | |
| | F | US- | | | |
| | G | US- | | | |
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FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

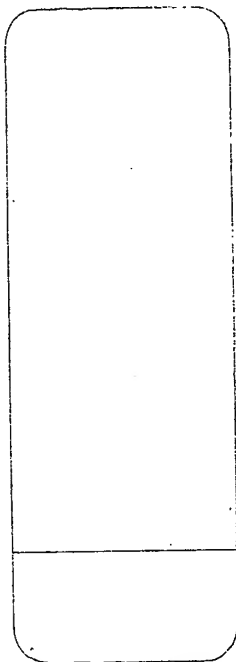
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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